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**From:** Aubee, Catherine [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=18E81C76BBA145F1948ED5641919DEB1-AUBEE, CATHERINE]  
**Sent:** 6/15/2017 5:49:48 PM  
**To:** Behrsing, Tracy [behrsing.tracy@epa.gov]  
**CC:** Hasan, Jafrul [Hasan.Jafrul@epa.gov]; Brinkerhoff, Chris [Brinkerhoff.Chris@epa.gov]  
**Subject:** RE: Can you be available today at 2PM for a call with R4 and NC risk assessors?

Tracy: Thank you!!! Very helpful.

Best,  
Catherine  
6221A East  
202.564.0631

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**From:** Behrsing, Tracy  
**Sent:** Thursday, June 15, 2017 1:48 PM  
**To:** Mayo, Kelly <Mayo.Kelly@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Brinkerhoff, Chris <Brinkerhoff.Chris@epa.gov>  
**Cc:** Hasan, Jafrul <Hasan.Jafrul@epa.gov>  
**Subject:** RE: Can you be available today at 2PM for a call with R4 and NC risk assessors?

Tala –

As a follow-up, here is a link to the dossier for the ammonium salt: <https://echa.europa.eu/registration-dossier/-/registered-dossier/2679/1>

The toxicological summary and individual studies are available under: "Toxicological Information" (see the blue bar on the left side of the website). Within the tox information, there are various subsections for different types of studies as well as a "Toxicological Summary" which shows the derivation of "Derived No Effect Levels" (DNELs) for workers and the general population via various routes of exposure. For the general population, the DNEL for oral exposure is 0.01 mg/kg/day based on a NOAEL of 1 mg/kg/day. According to the website, "The key study for DNEL calculation is an OECD 453 rat chronic toxicity study via oral administration. The NOAEL was determined to be 1 mg/kg bw/day, based on adverse effects in females at 500 mg/kg bw/day, and males at 50 mg/kg bw/day."

According the NC DHHS statement (see <http://www.wect.com/story/35653211/nc-dhhs-genx-would-pose-low-risk-to-human-health-based-on-2013-14-levels>), "...as part of the European chemical registration, a 2-year chronic toxicity and cancer study with rats was performed. They reported a Derived No Effect Level (DNEL) of 0.01 mg/kg bw/day. Based on U.S. risk assessment calculations, this corresponds to a concentration in drinking water of 70,909 ng/L of GenX- more than 100 times greater than the mean value of 631 ng/L detected in the Cape Fear River. Based upon these data, the GenX levels detected in 2013-2014 would be expected to pose a low risk to human health."

Please forward to others if you feel it's appropriate.

Tracy

**From:** Mayo, Kelly

**Sent:** Thursday, June 15, 2017 11:17 AM

**To:** Behrsing, Tracy <behrsing.tracy@epa.gov>; Aubee, Catherine <Aubee.Catherine@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>

**Subject:** RE: Can you be available today at 2PM for a call with R4 and NC risk assessors?

- For clarification, we DO NOT have all of the EPA created health study reviews from the former EPA staff that worked here. We DO have all the study summaries for the original studies submitted that we can work from – and other agencies have published the data as well, so I think we are OK.
- BUT - ALL of the previous reviewers are gone from EPA service so I want to make sure Tala understands back tracking issues. The table below is just an example of who worked on this.

Case	Program Mgr	Context of Request (i.e., what is the regulatory status of this case and what is the purpose of the request)	CCD Action Requested	Staff assigned
P-08-0508 & 0509	Rose Allison	Under Consent Order	Review request for Approval of Additional Respirators. CCD requests review by April 14. Is respirator ok?	Anjali & Justin
P-08-0508/0509	Allison	Study required under 5(e) Consent Order.	Review chronic Daphnid study.	Sara Pollack
P-08-0508/0509	Allison	Study required under 5(e) Consent Order.	Review 90-day study in rats	Jim Murphy
P-08-0508/0509	Allison	Study required under 5(e) Consent Order.	Review protocols for oral repro/dev tox screening study in mice	
P-08-0508/0509	Allison	Study required under 5(e) Consent Order.	Review protocol for chronic toxicity/carcinogenicity study, oral, rats and mice	Yin-tak Woo
P-08-0508/0509	Allison	Study required under 5(e) Consent Order.	Review 90-day study in mice.	Jim Murphy
P-08-0508/0509	Allison	Study required under 5(e) Consent Order.	Review company's proposal and rationale for the choice of species for the 2-yr study.	
P-08-0508/0509	Allison	Under 5(e) Consent Order	Review ADME study (rats and mice) and fish early life stage study	Sara P.
P-08-0508/0509	Allison	Under 5(e) Consent Order	Review of repro/dev study	Brenda
P-08-0508/0509	Allison	Under 5(e) Consent Order	Do they need to do the 2nd Tier of testing in the ADME study or will we waive it?	Leonard

P-08-0508/0509	Allison	Study required under 5(e) Consent Order.	As described in a letter from the submitter, the company is getting ready to terminate the study for the females because of too much mortality. Does RAD have an opinion on this issue?	Jennifer
P-08-0508/0509	Allison	Under 5(e) Consent Order	Is the 2-yr chronic/cancer study valid?	Yin-Tak
P-08-0508/0509	Allison	Under 5(e) Consent Order	Review 2-yr chronic/cancer study	Yin-Tak
P-08-0508/0509	Rose Allison	Under 5(e) Consent Order	Need written approval from Anjali of the respirators.	Anjali
P-08-0508/0509	Rose Allison	Under 5(e) Consent Order	Review respirator cartridge test protocol. Evaluate list of other workplace chemicals present.	Anjali
P-08-0508/509	Rose Allison	Under Consent Order	Respond to company's rebuttal of limitations place on cartridge respirators	Anjali Majd
P-08-0508/509	Rose Allison	Under Consent Order	Respond to company's rebuttal of limitations place on cartridge respirators	Anjali
P-08-0509	Allison		Review PK ADME	
P-08-0509	Allison	Study required under 5(e) Consent Order.	Attend mtg with company re 2-yr study on 2/7/13.	Yintak & Jennifer
P-08-0509	Allison	Study required under 5(e) Consent Order.	Review 2-yr study.	Yintak

-Kelly

Kelly E. Mayo-Bean, U.S EPA

Email: [mayo.kelly@epa.gov](mailto:mayo.kelly@epa.gov)

Phone: 202-564-7662

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**From:** Behrsing, Tracy

**Sent:** Thursday, June 15, 2017 10:58 AM

**To:** Aubee, Catherine <[Aubee.Catherine@epa.gov](mailto:Aubee.Catherine@epa.gov)>; Henry, Tala <[Henry.Tala@epa.gov](mailto:Henry.Tala@epa.gov)>

**Cc:** Mayo, Kelly <[Mayo.Kelly@epa.gov](mailto:Mayo.Kelly@epa.gov)>

**Subject:** RE: Can you be available today at 2PM for a call with R4 and NC risk assessors?

I will work on this. We were able to locate some of the HH tox reviews (not clear if they all were located to date) and Kelly printed the database summaries in table format. For now, on the CBI side, I will forward a copy of the standard review from 2008.

Tracy

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**From:** Aubee, Catherine

**Sent:** Thursday, June 15, 2017 10:55 AM

**To:** Henry, Tala <[Henry.Tala@epa.gov](mailto:Henry.Tala@epa.gov)>; Behrsing, Tracy <[behrsing.tracy@epa.gov](mailto:behrsing.tracy@epa.gov)>

**Cc:** Mayo, Kelly <[Mayo.Kelly@epa.gov](mailto:Mayo.Kelly@epa.gov)>

**Subject:** RE: Can you be available today at 2PM for a call with R4 and NC risk assessors?

Yes. Tracy, can you handle this for the HH tox reviews? I will work with Jeff on eco.

Best,  
Catherine

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**From:** Henry, Tala

**Sent:** Thursday, June 15, 2017 10:53 AM

**To:** Behrsing, Tracy <[behrsing.tracy@epa.gov](mailto:behrsing.tracy@epa.gov)>

**Cc:** Aubee, Catherine <[Aubee.Catherine@epa.gov](mailto:Aubee.Catherine@epa.gov)>; Mayo, Kelly <[Mayo.Kelly@epa.gov](mailto:Mayo.Kelly@epa.gov)>

**Subject:** Re: Can you be available today at 2PM for a call with R4 and NC risk assessors?

Can y'all pull together (print out)the reviews that RAD conducted on all the studies we received on this PMN as result of the CO

Sent from my iPhone

On Jun 15, 2017, at 10:30 AM, Behrsing, Tracy <[behrsing.tracy@epa.gov](mailto:behrsing.tracy@epa.gov)> wrote:

I have to leave today at 2:30 for an already scheduled appointment. Also – please include Chris Brinkerhoff as well on emails related to this subject (David cc'd him on some emails yesterday).

Thank you,

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**From:** Aubee, Catherine

**Sent:** Thursday, June 15, 2017 10:23 AM

**To:** Tobias, David <[Tobias.David@epa.gov](mailto:Tobias.David@epa.gov)>; Gallagher, Jeffrey <[Gallagher.Jeffrey@epa.gov](mailto:Gallagher.Jeffrey@epa.gov)>; Sarraino, Stephanie <[sarraino.stephanie@epa.gov](mailto:sarraino.stephanie@epa.gov)>; Macek, Greg <[Macek.Greg@epa.gov](mailto:Macek.Greg@epa.gov)>; Prothero, Scott <[Prothero.Scott@epa.gov](mailto:Prothero.Scott@epa.gov)>; Woo, Yintak <[Woo.Yintak@epa.gov](mailto:Woo.Yintak@epa.gov)>; Behrsing, Tracy <[behrsing.tracy@epa.gov](mailto:behrsing.tracy@epa.gov)>; Libelo, Laurence <[Libelo.Laurence@epa.gov](mailto:Libelo.Laurence@epa.gov)>; Mayo, Kelly <[Mayo.Kelly@epa.gov](mailto:Mayo.Kelly@epa.gov)>; Eisenreich, Karen <[Eisenreich.Karen@epa.gov](mailto:Eisenreich.Karen@epa.gov)>; Henry, Tala <[Henry.Tala@epa.gov](mailto:Henry.Tala@epa.gov)>

**Subject:** ALL: Can you be available today at 2PM for a call with R4 and NC risk assessors?

Per CCD request – a quick response is much appreciated.

Best,  
Catherine  
6221A East  
202.564.0631